

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW HAMPSHIRE

Bonnie Laderbush  
and George Laderbush

v.

Civil No. 20-cv-62-JD  
Opinion No. 2020 DNH 067

Ethicon, Inc., and  
Johnson & Johnson

O R D E R

Defendants Ethicon, Inc., and Johnson & Johnson  
(collectively, "Ethicon") move to exclude the testimony of Dr.  
Bruce Rosenzweig, M.D., under [Daubert v. Merrell Dow Pharm.,  
Inc.](#), 509 U.S. 579 (1993). Doc. 58. The plaintiffs, Bonnie and  
George Laderbush, object.

Standard of Review

To testify as an expert, a witness must be qualified to do  
so "by knowledge, skill, experience, training, or education."  
[Fed. R. Evid. 702](#). A qualified expert witness "may testify in  
the form of an opinion or otherwise" if the witness's  
"scientific, technical, or other specialized knowledge will help  
the trier of fact to understand the evidence or to determine a  
fact in issue;" if "the testimony is based on sufficient facts  
or data;" if "the testimony is the product of reliable  
principles and methods;" and if "the expert has reliably applied

the principles and methods to the facts of the case.” Id. Once the expert’s qualifications are established, the opinion is shown to be relevant, and the bases for the opinion are both sufficient and reliable, “the credibility and weight of the expert’s opinion [are] for the factfinder.” United States v. Jordan, 813 F.3d 442, 446 (1st Cir. 2016); see also Daubert, 509 U.S. at 597.

#### Background

The Laderbushes’ products liability case revolves around the safety of an implant called “TVT Exact,” which is marketed by Ethicon as a treatment for stress urinary incontinence. TVT Exact is constructed with a synthetic polypropylene mesh known as “Prolene”. The Laderbushes allege that the Prolene mesh used in TVT Exact is not suitable for use in treating stress urinary incontinence.

Dr. Bruce Rosenzweig is a pelvic surgeon and urogynecologist. In his expert reports, Dr. Rosenzweig offered several criticisms of the Prolene mesh, concluding that the Prolene mesh as used in the TVT Exact product was not suitable for treatment of stress urinary incontinence. Dr. Rosenzweig faulted the Prolene mesh in part because it was laser cut and therefore excessively rigid. Dr. Rosenzweig opined that a mechanically cut mesh would be less rigid. Dr. Rosenzweig asserted that the stiffness and rigidity of the mesh increases

complications such as chronic pain, chronic dyspareunia, erosions, and urinary dysfunction. Dr. Rosenzweig also offered opinions regarding Ethicon's reporting of adverse events and its furnishing of product warnings. He also outlined the various potential complications to implant recipients that could be caused, in his opinion, by the defects in TVT Exact.

### Discussion

Ethicon challenges Dr. Rosenzweig's opinion in four parts. In Part I of its motion, Ethicon challenges the reliability of Dr. Rosenzweig's opinion about how the Prolene mesh is cut. In Parts II and III, Ethicon challenges Dr. Rosenzweig's opinion about Ethicon's product warnings and adverse event reporting. In Part IV, Ethicon argues that expert testimony about complications that Ms. Laderbush did not suffer is irrelevant. The Laderbushes object to exclusion on the grounds raised in Parts I, II, and IV, but not to exclusion on the grounds raised in Part III. Ethicon did not file a reply.

#### A. Laser/Mechanical Mesh Cutting Opinion

In Part I of its motion to exclude, Ethicon argues that Dr. Rosenzweig's opinion about the inadequacy of a laser-cut mesh is unreliable because, in other cases, he has opined that a mechanically-cut mesh can cause the same complications as a

laser-cut mesh. The Laderbushes respond, arguing that Dr. Rosenzweig's criticisms of laser-cut meshes and mechanically-cut meshes are independent of each other. They contend that Dr. Rosenzweig's opinion has been that each type of cutting procedure presents unique issues that can, through different mechanisms, cause the same complications. They add that, even if Dr. Rosenzweig's opinions in other cases were contradictory, it would be an issue to be explored during cross-examination, not an issue warranting exclusion of the expert.

In support of its Daubert motion, Ethicon offered two brief excerpts of Dr. Rosenzweig's depositions in different cases. In one deposition, Dr. Rosenzweig merely notes that a laser-cut mesh and a mechanically-cut mesh can cause the same complications through different mechanisms. See doc. 58-6 at 4. In another deposition, Dr. Rosenzweig affirms that he has testified that both mechanically-cut and laser-cut meshes can be defective. Doc. 58-5 at 4. This testimony does not render Dr. Rosenzweig's opinion about the mesh cutting procedure unreliable. See Campos v. Safety-Kleen Systems, Inc., 98 F. Supp. 3d 372, 381 (D.P.R. 2015) (finding that expert's presentation of a contradictory opinion in a prior proceeding is not a challenge to the principles or methodology underlying an opinion but rather to the conclusion generated by the principles or methodology).

Ethicon further argues that Dr. Rosenzweig failed to cite any studies in support of his opinion, rendering it unreliable. Dr. Rosenzweig's opinion, however, is based on his own experience. Doc. 58-3 at 15 ("Based on my experience, training, review of the literature, and review of Ethicon's internal documents, the laser cut mesh in the TVT Exact is defective because it is too stiff and rigid."). Citation of studies in support of an opinion is a factor in determining reliability, but it is not a dispositive requirement, and Ethicon does not offer any developed argument challenging whether Dr. Rosenzweig's experience is sufficient. [Granfield v. CSX Transp., Inc.](#), 597 F.3d 474, 486 (1st Cir. 2010) ("CSXT makes much of the fact that Dr. Spector did not rely on peer-reviewed studies in his causation diagnosis. The mere fact of publication, or lack thereof, in a peer-reviewed journal is not a determinative factor in assessing the scientific validity of a technique or methodology on which an opinion is premised.").

Ethicon advances one final argument about Dr. Rosenzweig's cutting mechanism opinion, contending that the manner in which the Prolene mesh is cut is irrelevant to the claims in this case. The court, however, declines to decide whether, at this early stage, Dr. Rosenzweig's testimony on this point is irrelevant to the claims in this case. The court denies Ethicon's motion to exclude Dr. Rosenzweig's testimony on this

matter without prejudice to the filing of a motion in limine more fully addressing the issue at the appropriate time prior to trial.

B. Product Warnings Opinion

In Part II of its motion to exclude, Ethicon argues that Dr. Rosenzweig is not qualified to offer an opinion about the adequacy of the product warnings provided by Ethicon. The Laderbushes respond, arguing that Dr. Rosenzweig is qualified to opine about the adequacy of Ethicon's warnings.

In a similar MDL case, Judge Goodwin found that Dr. Rosenzweig was qualified to opine generally about the adequacy of the warnings provided with a mesh product similar to TVT Exact. [Huskey v. Ethicon](#), 29 F. Supp. 3d 691, 704 (S.D.W.Va. 2014) ("[A]s a urogynecologist, Dr. Rosenzweig is qualified to opine about the risks of the TVT-O and pelvic mesh surgery and whether those risks were adequately expressed on the TVT-O's [Instructions for Use]."). The court likewise finds that Dr. Rosenzweig is qualified to opine generally on the adequacy of Ethicon's warnings for TVT Exact. See id.; see also Armstead v. Coloplast Corp., 2020 WL 353576, at \*3 (M.D.N.C. Jan. 21, 2020) ("Dr. Rosenzweig has testified on the adequacy of [Instructions for Use] in past cases involving pelvic mesh devices, and there is no reason to think he has suddenly become unqualified to

render an opinion on the topic now.") (citations omitted). Therefore, Ethicon's motion to exclude Dr. Rosenzweig is denied as to its argument that Dr. Rosenzweig is unqualified to offer opinions about the adequacy of the warnings accompanying TVT Exact.

Ethicon also argues that Dr. Rosenzweig's product warnings opinion should be excluded because the Laderbushes' failure to warn claims should be dismissed. The court, however, has not dismissed the Laderbushes' failure to warn claims. Ethicon may renew its argument that Dr. Rosenzweig's opinion about the adequacy of TVT Exact's warnings is irrelevant if the court dismisses the failure to warn claims prior to trial.

C. Adverse Event Reporting Opinion

In Part III of its motion to exclude, Ethicon argues that the court should exclude Dr. Rosenzweig's adverse event reporting opinion. The Laderbushes do not contest Ethicon's motion to exclude on this ground. Doc. 64 at 6. Therefore, Ethicon's motion to exclude Dr. Rosenzweig's adverse event reporting opinions is granted.

D. Testimony About Complications (Part IV)

In Part IV of its motion to exclude, Ethicon contends that Dr. Rosenzweig's opinion should be excluded to the extent he asserts that TVT Exact can cause complications that Ms.

Laderbush did not experience. The Laderbushes respond, arguing that Ethicon's argument relates to relevance, which is outside the scope of a Daubert motion. They also contend that evidence of other complications is relevant, with the exception of the risk of cancer, which the Laderbushes concede should not be introduced.

As with Ethicon's argument about relevance in Part I of its motion to exclude, the relevance of testimony about possible complications of TVT Exact that Ms. Laderbush did not suffer is a matter that should be raised, if warranted, through a motion in limine closer to trial. Accordingly, the court denies Part IV of Ethicon's motion to exclude without prejudice.

#### Conclusion

Ethicon's motion to exclude the testimony of Dr. Rosenzweig under Daubert (doc. no. 58) is denied as to Part I (laser/mechanical mesh cutting opinion). The motion is denied with prejudice as to Ethicon's argument that Dr. Rosenzweig's opinions about the risks and benefits of laser cut and mechanically cut meshes are unreliable because he did not rely on peer-reviewed studies, but the motion is denied without prejudice as to the argument that the opinion is irrelevant. The motion is denied with prejudice as to Part II (product warning opinion), except Ethicon may renew its argument that the



opinion is irrelevant if the court dismisses the Laderbushes' failure to warn claims. The motion is granted as to Part III (adverse event reporting opinion). Finally, the motion is denied without prejudice as to Part IV (testimony about complications).

SO ORDERED.

  
Joseph A. DiClerico, Jr.  
United States District Judge

June 4, 2020

cc: Counsel of Record.